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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/779,703	02/09/2001	Rudolf Lucas	2551-55	6732	
. 7:	590 02/05/2003			<u>,                                     </u>	
NIXON & VANDERHYE P.C.			- EXAMINER		
8th Floor 1100 North Gle Arlington, VA			O HARA, EILEEN B		
Aimigion, VA	22201		ART UNIT PAPER NUMBER		
			1646	13	
			DATE MIAILED: 02/05/2003	DATE MAILED: 02/05/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

,		Application No.	Applicant(s)			
		09/779,703	LUCAS ET AL.			
	Office Action Summary	Examiner	Art Unit			
. •		Eileen B. O'Hara	1646			
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status 1)□	Responsive to communication(s) filed on					
2a)□		— · s action is non-final.				
3)□	, <del></del>		occution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims  4)⊠ Claim(s) 1-20 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
·	Claim(s) is/are objected to.					
·	•	election requirement				
8) Claim(s) <u>1-20</u> are subject to restriction and/or election requirement.  Application Papers						
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)						
2) Notic	te of Neterences Cited (PTO-692) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) Patent Application (PTO-152)			

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#### **DETAILED ACTION**

### Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given the statutory time for response to this office action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

In particular, the claims do not comply with 37 CFR § 1.822(d) which states that "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application". For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

#### Election/Restrictions

2. This application is a continuation and not a 371 of a PCT application, therefore the claims will be restricted under 35 U.S.C. 121.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-18, drawn to compositions of small peptides of human and mouse TNF- $\alpha$ , classified in class 350, subclass 351.
- II. Claims 19 and 20, drawn to method of treating oedema comprising administering compositions of small peptides of human TNF- α, classified in class 514, subclass
   2.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides can be used to generate antibodies, which is a materially different method from the method of treatment.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Advisory Information

Applicants are advised that claims 1, 10 and dependent claims will be rejected under 35 U.S.C. 112, second paragraph, because claims 1 and 10 recite regions of human or mouse TNF- $\alpha$  with no reference to what the specific sequences are.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600